

**REMARKS/ARGUMENTS:**

This Application is currently under final rejection. A prompt reconsideration of this Application is therefore respectfully requested.

Claims 44 and 48-51 remain in this application. Claim 49 has been amended to remove subject matter not examined by the Examiner and is now drawn to the terpineol species that was elected. Claims 1-9, 17-32 and 45 have been canceled. Claims 10-16, 33-43 and 46-47 have been withdrawn.

In the final office action dated July 14, 2005, the Examiner acknowledged the election of terpineol as the species. The Examiner issued a final rejection for claims 44 and 48-51 under 35 U.S.C. 102(b) as being anticipated Eini et al. The Examiner, based on new references, also rejected claims 44 and 48-51 under 35 U.S.C. 102(b) as being anticipated or rendered obvious by Nonomura et al. and rejected claims 44 and 48-51 under 35 U.S.C. 102(e) as being anticipated or rendered obvious by Bortlik et al.

Applicants also acknowledge safe receipt of the "Notice of References Cited" (form PTO-892) and the attached references.

No new matter has been introduced.

Applicants respectfully submit the amendments and additions of claims have overcome the objection and rejections for reasons set forth below:

***Claim rejections under 35 U.S.C. §102(b)***

The Examiner has rejected claims 44 and 48-51 under 35 U.S.C. 102(b) as being anticipated Eini et al. and further rejected claims 44 and 48-51 as being anticipated or rendered obvious by Nonomura et al. under 35 U.S.C. 102(b).

The Examiner has gone to great lengths to formulate an argument that the limitation of claim 44, wherein the composition is applied to the skin with a dermatological drug, is a portion of the preamble and should not to be given patentable weight. The examiner states that "a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art."

However, the examiner should be aware that the claim preamble must be read in the context of the entire claim (see MPEP 2111.02 (II)). The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966.

In this instance, the Examiner has not reviewed the entire record to gain an understanding of what the inventors actually invented. If the Examiner believes that the limitation of claim 44 that requires the composition to be applied in combination with a dermatological drug is in the preamble then this portion of the preamble gives life to the claims. As a result, "[I]f the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999).

Therefore, since the CYP1A inhibitor composition necessarily complements the administration of a dermatological drug to decrease the first pass effect of the drug, as described in the specification on page 7 line 11 through page 8 line 13, then the Examiner must give

weight to this limitation because this is what the inventors actually invented and intended to encompass by the claim.

Furthermore, since claim 44 encompasses the limitation where the CYP1A inhibitor composition is applied to the skin with a dermatological drug, the Eini et al. reference does not anticipate or render obvious the claimed composition.

To anticipate a claim, each and every element of the claim must be taught, either expressly or inherently, in a single prior art reference. Verdegaal Bros. v. union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987) (“a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”).

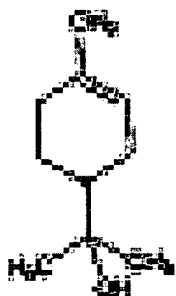
The Examiner cites Eini et al. as teaching all of the limitations of the claimed subject matter.

The limitations of the claimed subject matter for claims 44 and 48 include a CYP1A inhibitor known as terpineol, a carrier and a dermatological drug where the dermatological drug is applied with the terpineol/carrier and is retinoic acid or a retinoid. The limitations of the claimed subject matter for claims 49-51 include a free base or pharmaceutically acceptable salt of a dermal CYP1A inhibitor known as terpineol, a carrier and a dermatological drug; where claim 50 limits the dermatological drug to retinoic acid or a retinoid and where claim 51 limits the dermal CYP1A inhibitor/terpineol content in the composition to 10% by weight.

Eini et al. teach a composition of terpenoids in variable concentrations and a pharmaceutically or cosmetically acceptable carrier for repelling lice. In relation to claims 44 and 48, Eini et al. do not teach or even suggest a composition that encompasses a CYP1A inhibitor known as terpineol, with a carrier that is administered together with a dermatological

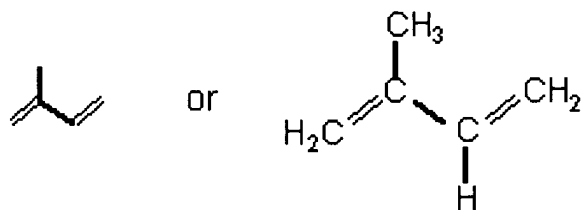
drug. In relation to claims 49-51, Eini et al. do not teach or even suggest the free base or a pharmaceutically acceptable salt of a dermal CYP1A inhibitor known as terpineol in combination with a carrier and a dermatological drug. Eini et al. also in no way suggest the composition containing retinoic acid or a retinoid.

Eini et al. are directed to terpenoids that represents a generic range of compounds. The Examiner's allegation that "terpineol is only an alcohol form that is inclusive of the generic terpenoid genus" is incorrect. Terpineol is 4-trimethyl-3-cyclohexene-1-methanol with a specific molecular formula of  $C_{10}H_{18}O$ . The chemical structure of terpineol can be found in Merck Index and is reproduced as follows:



Terpenoids, sometimes referred to as **isoprenoids**, are a large and diverse class of naturally occurring organic chemicals similar to terpenes, derived from five-carbon isoprene units assembled and modified in thousands of ways. Most are multicyclic structures which differ from one another not only in functional groups, but also in their basic carbon skeletons. These lipids can be found in all classes of living things, and are the largest group of natural products. See <http://en.wikipedia.org/wiki/Terpenoid>.

**Terpenes** are a class of hydrocarbons, produced by many plants, particularly conifers. They are major components of resin, and of turpentine produced from resin. The name "terpene" comes from "turpentine". Terpenes are derived from isoprene  $C_5H_8$  units and have the basic formula of multiples of it, i.e.,  $(C_5H_8)_n$ . The isoprene units can be arranged in a linear way or forming rings. See <http://en.wikipedia.org/wiki/Terpene>. The chemical structure of isoprene is shown as follows:



As a result, there are a multitude of compounds based on this generic structure that vary immensely. For example, the generic term "terpenoid" on the IUPAC website discloses such a broad range of compounds that the Nonomura et al. reference did not likely contemplate when using the term terpenoid.

Moreover, a generic formula, such as a terpenoid formula, that encompasses a vast number of compounds does not describe and thus does not anticipate all compounds embraced therein merely because those compounds are within the scope of the formula. In re Petering et al., 301 F.2d 676 (CCPA 1962). Therefore, in regard to the terpenoid teaching, Eini et al do not fulfill the requirements for an anticipation rejection under 35 U.S.C. 102(b) and therefore the rejection should be withdrawn.

The Examiner further rejected claims 44 and 48-51 as being anticipated or rendered obvious by Nonomura et al. under 35 U.S.C. 102(b).

The Nonomura et al. reference is divergent from the claims for a number of reasons. First, as discussed above, Nonomura et al. is directed to the generic class of compounds known as terpenoids rather than the specific species, terpineol, found in the claims.

Second, Nonomura et al. is directed to compositions that induce NADPH:cytochrome P450 monooxygenase in plants (abstract); whereas, the claimed composition is directed to inhibiting the dermal CYP1A in animals. In addition, the Nonomura et al. reference does not teach or even suggest the free base or a pharmaceutical salt as found in claims 44 and 49. The Nonomura et al. reference also does not disclose or even suggest a formulation where terpineol is present in an amount of about 10% by weight.

Therefore, with all of the inaccuracies found in the analysis of Nonomura et al., it cannot anticipate claims 44 and 48-51. This is because to anticipate a claim, each and every element of the claim must be taught, either expressly or inherently, in a single prior art reference. Verdegaal Bros., 814 F.2d at 631. Nonomura et al. do not accomplish this.

The examiner also states that one of skill in the art would be motivated to use terpineol as a terpenoid alcohol in a substitution for the separate elements terpenoid and alcohol of claim 32 in the Nonomura et al. reference. However, the only rationale for a statement such as this is the Examiner's misunderstanding of the definition of terpineol as discussed above. Moreover, one would not be motivated to select terpineol to increase industrial applicability because there is no direction given pointing out the specific species terpineol from the generic terpenoid genus.

***Claim rejections under 35 U.S.C. §102(e)***

The Examiner has rejected claims 44 and 48-51 under 35 U.S.C. 102(e) as being anticipated by Bortlik et al.

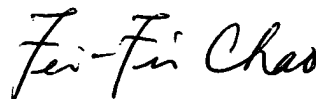
The arguments that apply to overcoming Nonomura et al. also apply to Bortlik et al. Primarily, Bortlik et al. has no reference to inhibiting dermal CYP1A. Also, Bortlik et al. only mentions the generic terpenoid genus and does not even remotely discuss terpineol. In addition, Bortlik et al. does not mention or even suggest the free base or pharmaceutically acceptable salt of terpineol. By failing to teach all of the claim limitations Bortlik et al. does not meet the requirement for a rejection under 35 U.S.C. 102(e). As a result, the rejection should be withdrawn.

Furthermore, the Bortlik et al. reference does not render obvious the claimed subject matter, as that subject matter is not taught in part or wholly nor is the subject matter even suggested. There is no motivation to claim the species as the Applicant has when the generic terpenoid genus is disclosed. Therefore, the claimed subject matter is not and would not be obvious to one of ordinary skill in the art.

In view of the foregoing, the rejections have been overcome and the claims are in condition for allowance, early notice of which is requested. Should the application not be passed for issuance, the examiner is requested to contact the applicant's attorney to resolve the problem.

Respectfully submitted,

Date: January 17, 2006



Fei-Fei Chao, Ph.D. (Reg. No. 43,538)  
Bingham McCutchen LLP  
Three Embarcadero Center, Suite 1800  
San Francisco, California 94111-4067  
Tel.: (202) 778-3179  
Fax: (202)-778-6155